04/02/24 BIG PHARMA

No Certain Cause of Healthy Teen's Death After COVID Vaccine, Coroner Rules + More

The Defender's Big Pharma Watch delivers the latest headlines related to pharmaceutical companies and their products, including vaccines, drugs, and medical devices and treatments. The views expressed in the below excerpts from other news sources do not necessarily reflect the views of The Defender. Our goal is to provide readers with breaking news that affects human health and the environment.

By The Defender Staff

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No Certain Cause of Healthy Teen's Death After COVID Vaccine, Coroner Rules

NZ Herald reported:

> A healthy 13-year-old who unexpectedly died 10 days after receiving a vaccination against COVID-19 had a "microscopic" amount of myocarditis in a crucial part of his heart. A coroner said the myocarditis — inflammation of the heart muscle — could have been caused by viruses found in the Wellington boy's heart tissue, but due to the short period of time since his immunization, the vaccine could not be ruled out as a possible cause.
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> The coroner released a report into the teenager's tragic death this morning, finding while the myocarditis caused his sudden death, he could not satisfactorily determine what caused the myocarditis.

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The boy, whose name and identifying details have been suppressed, died in October 2021. He was a fit, healthy and active child who had no significant medical issues and did not take any medication, Coroner Robin Kay said in his report.

"One of the pathologists commented that had [he] not died 10 days following a COVID-19 mRNA vaccination, the presence of inflammation in his heart and the detection of the viral DNA in his heart tissue from viruses known to cause myocarditis 'mean that the cause of death would have been confidently provided as viral myocarditis'," the report said.

Bavarian Nordic Begins Commercial Launch of Mpox Vaccine Jynneos in U.S.

Fierce Pharma reported:

After years of relying on the U.S. government to stockpile and distribute Jynneos, Bavarian Nordic is launching the mpox vaccine into the commercial market.

Jynneos, the only FDA-approved mpox vaccine, is now commercially available in the U.S., Bavarian Nordic announced Tuesday. The commercial rollout means that interested individuals can access the shot at local pharmacies and physician offices, in addition to the limited number of clinics designated by health authorities.

The launch builds on Jynneos' availability through public health channels since a mpox — then known as monkeypox — outbreak in 2022. It also follows a unanimous decision in October from the U.S. CDC's Advisory Committee on Immunization Practices to recommend Jynneos as a routine vaccination in adults at risk of mpox infection, backing the shot's use beyond an outbreak.

Mpox Vaccine Protection Quickly Fades; Boosters Necessary: Study

U.S. News & World Report reported:

Vaccine protection against mpox fades quickly in the human immune system, even in people who've received the full two-dose regimen, a new real-world study shows.

Antibody levels fell to low or near zero within the first few months of getting the vaccine, unless the person had previously received a smallpox vaccine, scientists reported Saturday at the European Congress of Clinical Microbiology and Infectious Diseases in Barcelona.

In the study, less than half of men without prior smallpox vaccination had any detectible antibodies to mpox (formerly known as monkeypox) 28 days after getting their second jab, the findings showed.

The researchers noted that no clinical trials are underway to investigate a booster dose for the mpox vaccine and that such trials are needed to inform public health guidelines.

U.S. Data Show Only 16% of Adults 27 to 45 Have Received an HPV Vaccine

CIDRAP reported:

Only 16% of US adults aged 27 to 45 have received the human papillomavirus (HPV) vaccine, with men, Hispanic respondents, and people with less education at even lower levels, according to a large survey study published last week in Human Vaccines & Immunotherapeutics.

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Although routine HPV vaccination was initially recommended for children aged 11 to 12 years, with catch-up vaccination through age 26, the Food and Drug Administration (FDA) expanded the age range in 2018 to adults 27 to 45 years, as well.

For the study, Duke University researchers analyzed data from the 2019 National Health Interview Survey, a nationally representative sample of the U.S. population. They write that this is the first study since the FDA age expansion to examine HPV vaccine uptake in a diverse sample of 27- to 45-year-olds from across the United States.

European Prosecutors Take Over Belgian Probe Into Pfizergate

Politico reported:

Top European prosecutors are investigating allegations of criminal wrongdoing in connection with vaccine negotiations between European Commission President Ursula von der Leyen and the CEO of Pfizer, according to a spokesperson from the Liège prosecutor's office.

Investigators from the European Public Prosecutor's Office (EPPO) have in recent months taken over from Belgian prosecutors investigating von der Leyen over "interference in public functions, destruction of SMS, corruption and conflict of interest," according to legal documents seen by POLITICO and a spokesperson from the Liège prosecutor's office. While EPPO's prosecutors are investigating alleged criminal offenses, no one has yet been charged in connection with the case.

The probe was originally opened by Belgian judicial authorities in the city of Liège in early 2023 after a criminal complaint lodged by local lobbyist Frédéric Baldan. He was later joined by the Hungarian and Polish governments — although the latter is in the process of withdrawing its complaint after the election win by a pro-EU government led by Donald Tusk, a Polish government spokesperson told POLITICO.

Baldan's complaint centered around an alleged exchange of text messages between von der Leyen and Pfizer boss Albert Bourla in the run-up to the EU's biggest vaccine deal at the height of the COVID-19 pandemic, in an affair dubbed "Pfizergate."

The New York Times, which first revealed that the exchange had taken place as the two leaders hashed out the terms of the deal, has launched a parallel lawsuit against the Commission after it refused to disclose the content of the messages following access to documents request.

Cheaper Private COVID Jabs May End Up as Costly as Pricier Ones, Say Experts

The Guardian reported:

Cheaper private COVID jabs could end up being just as expensive as their pricier alternative because the vaccine must be given in groups of five, experts have warned.

Boots and pharmacies that partner with the company Pharmadoctor are offering Pfizer/BioNTech jabs to those not eligible for a free vaccination through the NHS, with the former charging almost £100 a shot. The latter is also offering the latest Novavax jab, a protein-based vaccine, at a cost of about £50.

Concerns have been raised over the use of the Novavax jab, given each vial of the vaccine contains enough for five doses, which — once opened — must be used within 12 hours if refrigerated, and preferably immediately.

Prof Lawrence Young, a virologist at the University of Warwick, said the Novavax jab was just as effective in protecting against severe disease as the Pfizer/BioNTech and Moderna jabs, and it was also cheaper and easier to store. He said there was some evidence that protein-based jabs had fewer side effects, while other research had indicated a "mix and match" approach using different vaccines resulted in a better immune response.

Gritstone Shares Fall on Shaky Study Results for Colorectal Cancer Vaccine

BioPharma Dive reported:

> While cancer vaccines have historically disappointed in clinical testing, there's newfound momentum for the field as newer technologies yield stronger signs of potential.
>
> Like a handful of others, Gritstone is developing so-called neoantigen cancer vaccines — personalized shots that are engineered to target proteins specific to a patient's tumor. Several have produced encouraging results, most notably a melanoma vaccine Moderna and Merck & Co. are testing in a Phase 3 trial.
>
> In pursuit of that goal, Gritstone aims to link its vaccine to reductions in the amount of tumor genetic material circulating in the blood, known as circulating tumor DNA, or ctDNA. Executives previously discussed the possibility of seeking an accelerated approval if the ctDNA results from the company's ongoing study were strong enough.
>
> The data disclosed Monday falls short, however. In a February research note, ISI Evercore analyst Jon Miller set a benchmark of at least a 25% difference in ctDNA responses — defined as a reduction of 30% or more in ctDNA levels — between trial volunteers who received the shot, and those who didn't.

MDL Judge Allows Refiling of Daubert Challenges in Talcum Powder Lawsuits Five Years Later

AboutLawsuits.com reported:

> The U.S. District Judge presiding over all federal talcum powder cancer lawsuits is allowing Johnson & Johnson to reargue challenges to the admissibility of the plaintiff's expert witnesses testimony, which establishes that talc and asbestos particles in the products increase the risk of ovarian cancer, despite a previous ruling nearly five years ago that allowed the experts to testify.
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> Johnson & Johnson faces about 54,000 Baby Powder lawsuits and Shower-to-Shower lawsuits, each involving similar allegations that users were not adequately warned about the risk of developing ovarian cancer, mesothelioma and other injuries.
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> During the lengthy delay caused by Johnson & Johnson's bankruptcy maneuver, where the company attempted to shift all liability it faced to a subsidiary that immediately declared bankruptcy, Judge Wolfson retired and management of the talcum powder litigation was transferred to U.S. District Judge Michael A. Shipp.
>
> On March 27, Judge Shipp issued an order in the MDL docket granting the manufacturer a chance to again challenge plaintiff's expert testimony. He indicated that there have been recent changes to federal rules of evidence, as well as emerging new science, which makes "a full refiling of Daubert motions appropriate."

Abiomed Heart Pumps Linked to 49 Deaths

U.S. News & World Report reported:

> A new warning is being issued over a heart pump whose use could perforate the heart. The device has already been linked to over 100 injuries and 49 deaths.
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> These left-sided Impella heart pumps are made by Abiomed, a subsidiary of Johnson & Johnson MedTech. Abiomed posted the new warning on the devices on the U.S. Food and Drug Administration's website.
>
> "The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death," the statement said, although it adds that "this recall is a correction, not a product removal."
>
> Public Citizen, a consumer advocacy group, issued a statement calling for a full ban on the devices. Despite dozens of severe injuries and deaths, "the FDA has allowed them to remain in use," the group said. "Moreover, there are serious and ongoing concerns about whether there are clinically meaningful survival benefits that outweigh the risks of these left ventricular assist devices."

'The Heart Is Back,' Says Cardior CEO, as Novo's $1 Billion Deal Boosts Field

BioPharma Dive reported:

> When the Food and Drug Administration expanded approval of Novo Nordisk's weight loss medicine Wegovy to also protect heart health, the Danish drug giant had already made a pipeline commitment to developing new cardiovascular treatments.
>
> The March 8 approval was followed by news this week that Novo plans to buy German cardiovascular specialist Cardior Pharmaceuticals for north of $1 billion. "The heart is back," Cardior CEO and co-founder Claudia Ulbrich told PharmaVoice. "It's back for venture capital, and it's back for the pharma industry."
>
> As revenue from Wegovy sales pour in, Novo Nordisk is in a position to bolster its pipeline further. The deal to buy Cardior, whose lead candidate CDR132L is a RNA-based treatment for heart failure, serves that purpose.
>
> "Overall, the compound targets heart failure, and under this joint collaboration, we can address a large patient population," Ulbrich said.

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